STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION
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November 7, 2014

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for proposed amendments to Regulation 1591, *Medicines and Medical Devices*, which will be discussed at the Business Taxes Committee meeting on November 19, 2014. The proposed amendments will add devices that are implanted in the human body to mark the location of a medical condition to the definition of medicines.

Please feel free to publish this information on your website or otherwise distribute it to your associates, members, or other persons that may be interested in this issue.

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting at **10:00 a.m.** on **November 19, 2014** in Room 121 at the address shown above.

Sincerely,

Susanne Buehler

Susanne Buehler, Chief
Tax Policy Division
Sales and Use Tax Department

SB:map

Enclosures

cc: (all with enclosures)
Honorable Jerome E. Horton, Chairman, Fourth District
Honorable Michelle Steel, Vice Chair, Third District
Honorable Betty T. Yee, Member, First District (MIC 71)
Senator George Runner (Ret.), Member, Second District (via email)
Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel

(via email)
Mr. David Hunter, Board Member's Office, Fourth District
Ms. Jaclyn Appleby, Board Member's Office, Fourth District
Mr. Neil Shah, Board Member's Office, Third District
Mr. Tim Treichelt, Board Member's Office, Third District
Mr. Alan LoFaso, Board Member's Office, First District
Ms. Yvette Stowers, Board Member's Office, First District
Mr. Ramon Salazar, Board Member's Office, First District
Mr. Sean Wallentine, Board Member's Office, Second District
Mr. James Kuhl, Board Member's Office, Second District
Mr. Lee Williams, Board Member's Office, Second District
Mr. Alan Giorgi, Board Member's Office, Second District
Ms. Tanya Vandrick, Board Member's Office, Second District
Ms. Natasha Ralston Ratcliff, State Controller's Office
Ms. Cynthia Bridges (MIC 73)
Mr. Randy Ferris (MIC 83)
Mr. David Gau (MIC 101)
Mr. Marc Alviso (MIC 101)
Mr. Chris Lee (MIC 101)
Mr. John Thiella (MIC 73)
Mr. Jeffrey L. McGuire (MIC 43)
Mr. Robert Tucker (MIC 82)
Mr. Bradley Heller (MIC 82)
Mr. Lawrence Mendel (MIC 82)
Mr. Scott Claremon (MIC 82)
Ms. Kirsten Stark (MIC 50)
Mr. Clifford Oakes (MIC 50)
Mr. Bradley Miller (MIC 92)
Mr. Robert Wilke (MIC 50)
Mr. Michael Patno (MIC 50)

AGENDA — November 19, 2014 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action 1 – Agreed upon items Agenda, pages 2 - 16	Approve and authorize publication of proposed revisions to Regulation 1591 as agreed upon by interested parties and staff (except as indicated in Actions 2 - 4).
Action 2 — Definition of Medicines - 1591(a)(9)(A) Agenda, page 17	Approve and authorize publication of: Staff's recommendation that language be inserted at the end of Regulation 1591(a)(9) clarifying that medicines are further defined in subdivisions (b) and (c). **OR** The recommendation from Downey Smith & Fier (DSF) which clarifies the definition of medicines by placing the opening phrase referencing subdivision (c), along with suggested edits to Regulation 1591(a)(9)(A), at the end of the subsection. **OR** The recommendation from Equity Recovery Solutions Inc. (ERS) which amends the definition of medicines by placing the opening phrase referencing subdivision (c), along with suggested edits to Regulation 1591(a)(9)(A), at the end of the subsection.
Action 3 — "Permanently Implanted Articles" - 1591(b)(2) Paragraph 3 Agenda, pages 17 - 18	Approve and authorize publication of: Staff's recommendation to delete the last sentence in the last paragraph of subdivision (b)(2). **OR** ERS's recommendation to add language stating that specified devices are taxable only if intended to be implanted in the human body on a temporary basis.
Action 4 — Exclusions from the Definition of Medicines - 1591(c)(2) Agenda, pages 18 - 19	Approve and authorize publication of: Staff's recommendation to leave Regulation 1591(c)(2) intact. **OR** DSF's recommendation to add the parenthetical language that articles which are fully implanted would not be excluded from the definition of medicines. **OR** ERS's recommendation to add language stating that articles which are fully and permanently implanted or their fully worn components would not be excluded from the definition of medicines.

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Regulation 1591, Medicines and Medical Devices

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Action 1 — Agreed Upon Items	(a) Definitions. (1) Administer. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means. (2) Dispense. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice. (3) Furnish. "Furnish" means to supply by any means, by sale or otherwise. (4) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in s~~S~~ection 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code. (A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer. (B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an~~in~~ incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for

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	purposes of this subdivision. (C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of d~~D~~ivision 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility. (5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of s~~S~~ection 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law." (6) Pharmacy. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of s~~S~~ection 4037 of the Business and Professions Code. (7) Prescription. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician,

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	dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following: (A) The name or names and address of the patient or patients. (B) The name and quantity of the drug or device prescribed and the directions for use. (C) The date of issue. (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed. (E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients. (F) If in writing, signed by the prescriber issuing the order. (8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to s~~S~~ection 2065 of the Business & Professions Code, when acting within the scope of that section. (9) Medicines. “Medicines” means: **[See Action 2, page 17 for proposed amendments]** (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the

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	human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, or (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation. For purposes of subdivision (a)(9)(A), products, "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration. Medicines are further defined in subdivisions (b) and (c) below. (b) "Medicines." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items: (1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). "Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics,

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	"dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract. (2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. <u>In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines.</u> An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb <u>or mark the location of a medical condition,</u> and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted

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	catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture. **[See Action 3, Page 17 for proposed amendments to the last paragraph (#3) of (b)(2)]** (3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369(c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). (4) Orthotic Devices. Orthotic devices and their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace

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	bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation. Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of Paris, stone, or wax, and may be manually constructed or fabricated using electronic technology. “Custom-made biomechanical foot orthosis” do not include: (A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification; (B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or (C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character. (5) Prosthetic Devices. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and

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	Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN. Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuffs, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist. Prosthetic devices that do not qualify as medicines include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials

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	and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property. (6) Drug Infusion Devices. Programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). (c) Exclusions from the Definition of "Medicines." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property. (1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances. **[See Action 4, Page 18, for proposed amendments to (c)(2)]** (2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

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	(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with s~~S~~ection 23000, of the Business and Professions Code). (d) Application of Tax - In General Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions: (1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or (2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or (3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or (4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or (5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or (6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines.

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	The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines. (e) Specific Tax Applications. (1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist. (2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished. (3) Health Facility. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines. (4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles,

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	boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax. This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax. (5) Antimicrobial Agents Used by Hospital Personnel. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in

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	the treatment of the patient and the sale or use of these products is subject to tax. (6) Vitamins, Minerals, Herbs, and Other Such Supplements. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6). (7) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) ~~of Regulation 1591~~. (8) Diagnostic Substances, Test Kits, and Equipment. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (-"in vitro") in an artificial environment. They are not administered in the living body (-"in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369. Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

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Action Item	Proposed Regulation 1591 as agreed upon by interested parties and staff
	(f) Insurance Payments (1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer. (2) Medicare (A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government. (B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax. (3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

AGENDA — November 19, 2014 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Proposed Regulation 1591 as agreed upon by interested parties and staff
	(g) Records. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities. Pursuant to s~~S~~ection 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records. (1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of s~~S~~ection 6369: Name of purchaser Name of doctor Date of sale Item sold The sale price (2) "Double Deduction" Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program. (3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667

AGENDA — November 19, 2014 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Alternative 1 – Staff Recommendation	Alternative 2 – Regulatory Language Proposed by Downey Smith & Fier	Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.
Action 2 — Definition of Medicines - 1591(a)(9)(A)	(a)(9) *[beginning after subdivisions (a)(9)(A) and (a)(9)(B), as the third paragraph]* Medicines are further defined in subdivisions (b) and (c) below.	(9) Medicines. "Medicines" means: (A) ~~Except where taxable for all uses as provided in subdivision (c), a~~Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses, or	(9) Medicines. "Medicines" means: (A) ~~Except where taxable for all uses as provided in subdivision (c), a~~Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, except where taxable as provided in subdivision (c), or
Action 3 — "Permanently Implanted Articles" - 1591(b)(2) Paragraph 3	(b)(2) *[beginning at paragraph 3]* Implantable articles that do not qualify as "permanently" implanted medicine8s include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during the surgery and	[No alternative language provided for this section.]	(b)(2) *[beginning at paragraph 3]* Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during the surgery and

AGENDA — November 19, 2014 Business Taxes Committee Meeting

Regulation 1591, Medicines and Medical Devices

Action Item	Alternative 1 – Staff Recommendation	Alternative 2 – Regulatory Language Proposed by Downey Smith & Fier	Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.
Action 3 — (Continued) "Permanently Implanted Articles" - 1591(b)(2) Paragraph 3	recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. ~~The sale or use of these items is subject to tax.~~		recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax, if intended for temporary placement.
Action 4 — Exclusions from the Definition of Medicines - 1591(c)(2)	[No alternative language is recommended by staff for this section.]	(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article (unless the product is fully implanted into the human body) or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other	(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof that are fully and permanently implanted or their fully worn components. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts,

Action Item	Alternative 1 – Staff Recommendation	Alternative 2 – Regulatory Language Proposed by Downey Smith & Fier	Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.
Action 4 — (Continued) Exclusions from the Definition of Medicines - 1591(c)(2)		than those fully worn on the patient), thermophore pads, nor foot orthoses.	traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

Issue Paper Number **14-006**

- ☐ Board Meeting
- ☒ Business Taxes Committee
- ☐ Customer Services and Administrative Efficiency Committee
- ☐ Legislative Committee
- ☐ Property Tax Committee
- ☐ Other

BOARD OF EQUALIZATION
KEY AGENCY ISSUE

Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of "medicines" includes devices implanted to mark the location of a medical condition?

II. Alternative 1 - Staff Recommendation

Staff recommends that the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivision (a)(9) clarifying that medicines are further defined in subdivisions (b) and (c) and that the last sentence of subdivision (b)(2) be removed to clarify that the specific articles that do not qualify as permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

III. Other Alternative(s) Considered

Staff received comments from Downey, Smith & Fier (DSF) and Equity Recovery Solutions, Inc. (ESR) in response to staff's second discussion paper. (See Exhibits 3 & 4, respectively.) Their proposed language is presented as Alternatives 2 and 3.

Alternative 2 – DSF Recommendation

DSF submitted proposed language for two subdivisions. They recommend altering and relocating language in subdivision (a)(9)(A), specifically the reference to subdivision (c). They also add parenthetical language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for fully implanted articles. (See Exhibit 3 and Agenda, Action Items 2 and 4.)

Alternative 3 –ERS Recommendation

ERS submitted proposed language for three subdivisions. They also recommend altering and relocating language in subdivision (a)(9)(A). In addition, ERS proposes to add language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for articles which are "fully and permanently implanted or their fully worn components." Lastly, ERS proposes adding the language "if intended for temporary placement" to the end of the last sentence in subdivision (b)(2). (See Exhibit 4 and Agenda, Action Items 2, 3 and 4.)

IV. Background

General

Revenue and Taxation Code section (section) 6369, as interpreted and implemented by Regulation 1591, provides that the sale or use of medicines is not subject to tax if they are sold or otherwise transferred under specified circumstances. Section 6369, subdivision (b), defines "medicines" as "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." It further provides that certain items are excluded from the definition of medicines, including "(2) Articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." However, section 6369, subdivision (c), includes additional specific items that are, notwithstanding subdivision (b), considered to be medicines.

Regulation 1591 has been revised over the years to clarify the definition of "medicines," but in general it closely resembles the structure of section 6369. Regulation 1591, subdivision (a)(9), defines "medicines" as follows:

> (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or
>
> (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also include certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (b), in addition to defining and providing examples of preparations and similar substances, includes several categories of articles, devices and appliances which are included in the definition of medicines, either generally or for specific uses and provides examples of specific items that are included in or excluded from those categories. Additional exclusions from the definition of medicines are identified in subdivision (c).

February 2014 Board Meeting

During the February 2014 Board Meeting, the Members heard a sales and use tax appeal hearing involving breast tissue markers (BTMs). At issue was whether BTMs are medicines and therefore exempt from tax when sold or furnished under the prescribed conditions. The BTMs discussed in the hearing were purchased from an out-of-state vendor. The hospital paid use tax to the Board and then filed claims for refund for the use tax paid.

BTMs are sterile disposable medical devices that are comprised of an introducer needle and applier as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. A doctor inserts the BTM in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by ultrasound, MRI or other imaging methods at a future date.

During the hearing, the taxpayer's representative stated the BTMs are devices that are fully implanted in a person and are approved for marketing by the FDA to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition, and therefore meet the definition of medicines provided in Regulation 1591, subdivision (a)(9)(A). The taxpayer's representative also stated that the BTMs were not articles excluded from the definition of medicine by subdivision (c)(2).

Conversely, staff stated that BTMs are "devices" which are "articles" excluded under subdivision (c)(2). Furthermore, though they are permanently implanted in the human body and aid patients during their medical treatments, BTMs do not assist the functioning of any organ, artery, vein or limb as currently specified by subdivision (b)(2), *Permanently Implanted Articles*, as a requirement to be deemed exempt. Finally, staff contended that BTMs were not "approved" by the FDA.

The Board unanimously voted in favor of the claimant. During the discussion, it was recommended that staff provide a narrow clarification of Regulation 1591 to explore the possibility of not having to apply tax to these types of articles. The Board directed the Business Taxes Committee (BTC) staff to clarify the provisions of Regulation 1591 as it relates to Class II medical devices that are fully implanted.

V. Discussion

Does the definition of medicines contained in subdivision (a)(9) need clarification?

At the February 2014 Board meeting, the Board discussed the definition of medicines as it pertains to medical devices and the complicated nature of FDA classifications of those medical devices. Pursuant to the Board's instructions, in the first discussion paper, staff suggested altering the wording of the phrase "Except where taxable for all uses as provided in subdivision (c)" found at the beginning of subdivision (a)(9)(A) and moving it to the end of the subdivision. Staff also added language to subdivision (a)(9) that would clarify the meaning of the term "approved by United States Food and Drug Administration."

During the first interested parties meeting in June, DSF contended that subdivision (a)(9)(A) is confusing, specifically, that it is not clear to taxpayers that they must look to subdivisions (b) and (c) to determine if a product qualifies as a medicine under subdivision (a)(9)(A). They further stated that moving the phrase "Except where taxable for all uses as provided in subdivision (c)" to the end of the subdivision did not improve its clarity. DSF submitted alternative language.

In the second discussion paper, the proposed revision to subdivision (a)(9)(A) was removed. Staff instead recommended that a single sentence be added to the end of subdivision (a)(9) indicating that medicines are further defined in subdivisions (b) and (c). Staff believes the inclusion of the sentence will emphasize that subdivisions (a), (b), and (c) all need to be considered when determining whether a product meets the definition of medicines.

Most medical devices are deemed Class II devices by the FDA. They generally are subject to Section 510(k) of the Food, Drug and Cosmetic Act, which requires the device manufacturers to notify the FDA of their intent to market a medical device. This is known as "premarket notification" and demonstrates that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR § 807.92(a)(3)) that is not subject to premarket approval. Generally, a new device that contains new materials or differs in design from products already on the market requires premarket approval by the FDA.

At the February 2014 Board meeting, it was noted that a device may not require pre-market approval when similar devices, which may have required premarket approval, are already on the market. Additionally, it was noted that although Class II devices are generally subject to premarket notification,

and Class III devices are generally subject to premarket approval, such is not always the case. As a result, staff's position that "approved by the U.S. Food and Drug Administration" refers only to premarket approval, could exclude devices of the type that the Board intended to include in the definition of medicine and that met all of the other elements of subdivision (a)(9)(A). Therefore, staff recommends the inclusion of language that defines "approved by the U.S. Food and Drug Administration" at the end of subdivision (a)(9), to provide needed clarity. No opposition to this language was received from interested parties.

Should permanently implanted articles that mark the location of a medical condition be included in the definition of medicines?

The BTM manufacturer's marketing materials indicated that BTMs could remain in the human body for an indefinite amount of time, therefore staff considers them to be permanently implanted. Staff proposed a revision to include permanently implanted articles that mark a location of a medical condition in the definition of medicines. Staff determined that the appropriate placement for revised language is in Regulation 1591, subdivision (b)(2), *Permanently Implanted Articles*. Staff also included BTMs as a specific example of a device that performs such a function. This recommendation is supported by interested parties.

Does the definition of medicines contained in subdivision (b)(2) need clarification?

The final paragraph of subdivision (b)(2) lists articles that "do not qualify as "permanently" implanted medicines," and states: "The sale or use of these items is subject to tax." During the interested parties process, ERS contended that such items may meet the definition of medicines under a different subdivision. Staff agreed with ERS that some devices, while determined not to be permanently implanted medicines, may meet the definition of medicines under a different part of subdivision (b). Believing the confusion stems from the final sentence in (b)(2), staff proposes deleting the sentence entirely. Staff presented this amendment at the second interested parties meeting held in September.

ERS submitted language to amend the subdivision. Instead of removing the final sentence, their proposal modified the subdivision to state:

> The sale or use of these types of items would be subject to tax, if intended for temporary placement.

Staff considered the language proposed, but concluded that it should not be added. The addition of the phrase to the existing sentence would create confusion and even nullify the preceding language regarding "permanently" implanted articles contained within subdivision (b)(2). For instance, some of the items listed in the paragraph fail to meet the definition of medicine contained in subdivision (b)(2), not because they are not permanently implanted, but because they do not assist the functioning of a natural organ, artery, vein or limb. Additionally, the use of the word "intended" would expand the definition of medicine by implying that an item would need only to be intended for permanent use to meet the definition. Adding an intent element would also add ambiguity and make it difficult for audit staff to determine if an article was considered permanently implanted.

Should an exception for fully implanted or fully and permanently implanted articles be added to the exclusion from the definition of medicines contained in subdivision (c)(2)?

Both DSF and ERS have concerns with existing language used in subdivision (c)(2) and have submitted revisions for consideration. During the last interested parties meeting, DSF indicated they believe fully implanted products were ruled exempt by the Board, at the February 2014 Board meeting. DSF's

language adds an exception for articles excluded from medicines if "the product is fully implanted into the human body." ERS proposes additional language to be inserted at the end of a list of articles excluded from the definition of medicines. Language from ERS provides an exception if the articles "are fully and permanently implanted or their fully worn components."

Staff cannot incorporate either submission because they would expand the definition of medicine in conflict with the plain language of the statute. The language used in subdivision (c)(2) is taken directly from section 6369, subdivision (b)(2). Thus the interested parties are seeking to add an exception that does not exist under the statutory language. The revisions would effectively include in the definition of medicines all products fully implanted but section 6369, subdivision (c)(2), specifically states that only permanently implanted articles that "assist the functioning of any natural organ, artery, vein, or limb" are medicines. Accordingly, the proposed language would expand the definition of medicine beyond the statute, making redundant the narrower definition of medicines set forth in Regulation 1591, subdivision (b)(2). Both alternatives could also have a material negative impact on state revenues, as the revenue impact report shows in Exhibit 1.

VI. Alternative 1 - Staff Recommendation

A. Description of Alternative 1

Staff recommends that the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines, to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval, to insert language in subdivision (a)(9) indicating that medicines are further defined in subdivisions (b) and (c) and to delete the final sentence in subdivision (b)(2) to clarify that articles that do not qualify as a permanently implanted medicine may meet the definition of medicines under a different subdivision.

B. Pros of Alternative 1

The proposed revisions narrowly clarify that permanently implanted devices that mark the location of a medical condition are included in the definition of medicines. Staff believes its recommendations also provide clarity with regard to the application of subdivision (a)(9)(A) and remove language from subdivision (b)(2) that could cause confusion with regard to the application of tax to certain items.

C. Cons of Alternative 1

Interested parties disagree with staff's decision not to add language to subdivisions (c)(2) and (b)(2) regarding articles "fully" or "fully and permanently" implanted. Interested parties believe the changes sought are in keeping with the Board's unanimous decision at the February 2014 appeals hearing and its direction to staff to clarify Regulation 1591 as it relates to fully implanted devices.

D. Statutory or Regulatory Change for Alternative 1

No statutory change is required. However, staff's alternative will require a regulatory change.

E. Operational Impact of Alternative 1

Staff will publish the proposed amendments to Regulation 1591 and thereby begin the formal rulemaking process. Once proposed amendments are approved by the Office of Administrative Law,

staff will update the Board of Equalization (BOE) website information, Publication 27, *Drug Stores* and Publication 45, *Hospitals and Other Medical Facilities*.

F. Administrative Impact of Alternative 1

1. Cost Impact

The workload associated with publishing the regulation is considered routine. Any corresponding cost would be absorbed within the Board's existing budget.

2. Revenue Impact

Negligible. See Revenue Estimate (Exhibit 1).

G. Taxpayer/Customer Impact of Alternative 1

Staff believes its proposal clarifies the definition of medicines for taxpayers. Staff will update the BOE website and publications that provide information regarding Regulation 1591 to taxpayers.

H. Critical Time Frames of Alternative 1

None.

VII. Alternative 2 – DSF Recommendation

A. Description of Alternative 2

DSF recommends that subdivision (a)(9)(A) be revised by amending the reference to subdivision (c) and moving it to the end of the paragraph. In addition, they suggest language for subdivision (c)(2) to state that products, fully implanted in the human body, would be an exception to the exclusion contained in the subdivision.

B. Pros of Alternative 2

- This alternative provides that products which are fully implanted in the human body would not be excluded from the definition of medicines.
- DSF believes these revisions are consistent with the Board's decision favoring their client in the appeals case involving BTMs.

C. Cons of Alternative 2

- Staff believes that the DSF proposed revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute.
- Staff believes the change would expand the definition of medicine beyond the statute to include all fully implanted items and have a negative revenue impact.
- Staff believes that amending the reference to subdivision (c) and moving it to the end of subdivision (a)(9)(A) would make it harder for a taxpayer to understand that they must look to subdivision (c) when applying subdivision (a)(9)(A).

D. Statutory or Regulatory Change for Alternative 2

A statutory change would be required to make the regulatory revision to subdivision (c)(2) being sought by DSF because this revision would expand the definition of medicine to include all fully implanted products.

E. Operational Impact of Alternative 2

Same as Alternative 1.

F. Administrative Impact of Alternative 2

1. Cost Impact

Same as Alternative 1.

2. Revenue Impact

Sizable economic impact. See Revenue Estimate (Exhibit 1).

G. Taxpayer/Customer Impact of Alternative 2

DSF believes that their alternative properly includes fully implanted products in the definition of medicines and would be in keeping with the Board's decision during the February 2014 Board Meeting.

H. Critical Time Frames of Alternative 2

None.

VIII. Alternative 3 – ERS Recommendation

A. Description of Alternative 3

ERS recommends that subdivision (a)(9)(A) be revised by moving the reference to subdivision (c) to the end of the paragraph and removing from it the phrase "for all uses." In addition, ERS proposes adding a phrase to the final sentence of subdivision (b)(2) indicating that the items specified as not constituting permanently implanted medicines are taxable only if intended for temporary implantation. Finally, ERS suggests language for subdivision (c)(2) to state that products, fully and permanently implanted in the human body, would be an exception to the exclusions in the subdivision.

B. Pros of Alternative 3

- ERS believes their provisions provide that products which are fully and permanently implanted in the human body would not be excluded from the definition of medicines.
- ERS believes their revisions will allow staff to use their judgment, when appropriate, in working with taxpayers to analyze medical products.

C. Cons of Alternative 3

- Staff believes that the ERS proposed revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute.
- Staff believes the change would expand the definition of medicine beyond the statute to include all fully implanted items and have a negative revenue impact.
- Staff believes that moving the reference to subdivision (c) to the end of subdivision (a)(9)(A) would make it harder for a taxpayer to understand that they must look to subdivision (c) when applying subdivision (a)(9)(A). Additionally, removing the phrase "for all uses" will actually narrow the definition of medicines in conflict with the intent of the subdivision.

- Staff believes the change to subdivision (b)(2) would create contradictions within the subdivision, would expand the definition and make it more ambiguous by adding an intent element, and would create unnecessary complexity.

D. Statutory or Regulatory Change for Alternative 3

A statutory change is required to make the regulatory revisions being sought by ERS.

E. Operational Impact of Alternative 3

Same as Alternative 1.

F. Administrative Impact of Alternative 3

1. Cost Impact

Same as Alternative 1.

2. Revenue Impact

A material economic impact. See Revenue Estimate (Exhibit 1).

G. Taxpayer/Customer Impact of Alternative 3

ERS believes that their alternative properly includes fully and permanently implanted products in the definition of medicines. They also consider that their revisions clarify confusing language that incorrectly implies specific products are taxable for all uses.

H. Critical Time Frames of Alternative 3

None.

Preparer/Reviewer Information

Prepared by: Tax Policy Division, Sales and Use Tax Department

Current as of: 10/30/14

BOARD OF EQUALIZATION
REVENUE ESTIMATE

Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of "medicines" includes devices implanted to mark the location of a medical condition?

II. Alternative 1 - Staff Recommendation

Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivision (a)(9) clarifying that medicines are further defined in subdivisions (b) and (c) and that the last sentence of subdivision (b)(2) be removed to clarify that the specific articles that do not qualify as being permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

III. Other Alternative(s) Considered

Staff received comments from Downey, Smith & Fier (DSF) and Equity Recovery Solutions, Inc. (ERS) in response to staff's second discussion paper. (See Exhibits 3 and 4, respectively.) The suggested revisions to staff's proposed language which staff did not include in its recommendations are presented as Alternatives 2 and 3.

Alternative 2 – DSF Recommendation
DSF recommends altering and relocating the language used in subdivision (a)(9)(A), specifically the reference to subdivision (c). They also add parenthetical language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for fully implanted articles

Alternative 3 – ERS Recommendation
ERS also recommends altering and relocating the language used in subdivision (a)(9)(A) which references subdivision (c). In addition, ERS proposes to add language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for articles which are "fully and permanently implanted or their fully worn components." Lastly, ERS

proposes adding the language "if intended for temporary placement" to the end of the last sentence to subdivision (b)(2).

Background, Methodology, and Assumptions

Alternative 1 – Staff Recommendation

Staff recommendation would have a relatively insignificant impact on revenue. Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivisions (b) and (c) and the last sentence of (b)(2) be removed to clarify that the specific articles that do not qualify as permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

Staff recommendation would expand the number of permanently implanted devices included in the definition of medicines in a limited manner when they are used to mark the location of a medical condition. Staff believes their recommendation also provides clarity with regard to the application of subdivision (a)(9)(A) and removes language from subdivision (b)(2) that could cause confusion with regard to the application of tax to certain items.

Staff recommendation could have a negligible impact on revenue in the thousands of dollars based on the amount of refund claims the Board of Equalization has processed within the last eight months.

Other Alternatives Considered

Alternative 2 – DSF Recommendation

The DSF recommendations would have a significant impact on revenue. DSF recommends that the (a)(9)(A) definition of medicines be revised by amending the reference to subdivision (c) and moving it to the end of the paragraph. In addition, they suggest language for subdivision (c)(2) to state that products, fully implanted in the human body, would be an exception to the exclusions in the subdivision.

This provision provides that products which are fully implanted in the human body would not be excluded from the definition of medicines. In addition, DSF believes these revisions to be what the Board indicated in their decision favoring their client in their case involving BTMs.

However, staff contends that the revision to subdivision (c) is not supported by Revenue and Taxation Code section 6369 as the language used in subdivision (c) is taken directly from the statute. Further, staff believes the change would also expand the definition of medicines beyond the statute to include all fully implanted items and have a negative revenue impact.

Alternative 2 will have a significant impact on revenues in the millions of dollars, based on a pending claim for refund of $35,000 for portacath implants from one hospital over an audit period of 2 ½ years. A portacath is currently excluded from the definition for medicines. A portacath is a small medical appliance that is installed beneath the skin and used for hemodialysis patients, and for

administering medication such as chemotherapy. If we extrapolate the claim total of $35,000 to a population of over 500 hospitals in California the annual revenue impact could be as much as $7 million ($35,000 / 30 months x 12 months x 500 hospitals = $7 million).

Alternative 3 – ERS Recommendation

Alternative 3 would have a significant impact on revenue. ERS recommends that subdivision (a)(9)(A) be revised by moving the reference to subdivision (c) to the end of the paragraph and removing the phrase "for all uses." In addition, ERS proposes adding a phrase to the final sentence of subdivision (b)(2) indicating items specified as not constituting permanently implanted medicines are taxable only if intended for temporary implantation. Finally, ERS suggests language for subdivision (c)(2) to state that products, fully and permanently implanted in the human body, would be an exception to the exclusions in the subdivision.

This provision provides that products which are fully and permanently implanted in the human body would not be excluded from the definition of medicines. ERS believes their revisions will allow staff to use their judgment, when appropriate, in working with taxpayers to analyze medical products.

However, staff contends that the revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute. Further, staff believes the change would also expand the definition of medicines beyond the statute to include all fully implanted items and have a negative revenue impact.

The ESR recommendations will have a significant impact on revenues in the millions of dollars, based on a pending claim for refund of $35,000 for portacath implants from one hospital over an audit period of 2 ½ years. As with the DSF recommendation, if we extrapolate the claim total of $35,000 to a population of over 500 hospitals in California the annual revenue impact could be as much as $7 million ($35,000 / 30 months x 12 months x 500 hospitals = $7 million).

Revenue Summary

Alternative 1 – staff recommendation will have relatively insignificant revenue impact of thousands of dollars annually.

Alternative 2 – DSF recommendation will have a significant impact on revenue in the millions of dollars annually.

Alternative 3 – ERS recommendation will also have a significant impact on revenue in the millions of dollars annually.

Preparation

Mr. Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. This estimate has been reviewed by Mr. Mark Durham, Manager, Research and Statistics Section, Legislative and Research Division, and Ms. Susanne Buehler, Chief, Tax Policy Division, Sales and Use Tax Department. For additional information, please contact Mr. Benson at (916) 445-0840.
Current as of October 30, 2014

§ 1591. Medicines and Medical Devices.

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in s~~S~~ection 1250 of the Health and Safety Code, and also includes “clinic” as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that “health facility” means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that “clinic” means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an~~in~~ incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or

contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of dDivision 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of sSection 4200 of the Business & Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) Pharmacy. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of sSection 4037 of the Business and Professions Code.

(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state and given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of

California and includes an unlicensed person lawfully practicing medicine pursuant to s~~S~~ection 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~ United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

For purposes of subdivision (a)(9)(A), products, "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(b) "Medicines." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food

provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb or mark the location of a medical condition, and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins; dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. ~~The sale or use of these items is subject to tax.~~

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369(c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthotic Devices. Orthotic devices and their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts, and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. “Custom-made biomechanical foot orthosis” means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of Paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

“Custom-made biomechanical foot orthosis” do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) Prosthetic Devices. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuffs, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as medicines include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) Drug Infusion Devices. Programmable drug infusion devices to be worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section

6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from the Definition of "Medicines."

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with s~~S~~ection 23000, of the Business and Professions Code).

(d) Application of Tax - In General

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) Specific Tax Applications.

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) Health Facility. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or

other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) Antimicrobial Agents Used by Hospital Personnel. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) Vitamins, Minerals, Herbs, and Other Such Supplements. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) ~~of Regulation 1591~~.

(8) Diagnostic Substances, Test Kits, and Equipment. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (-"in vitro") in an artificial environment. They are not administered in the living body (-"in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under

stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) Records.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to ~~s~~Section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of ~~s~~Section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "Double Deduction" Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Authority cited: ~~s~~Section 7051, Revenue and Taxation Code. Reference: ~~s~~Sections 6006 and 6369, Revenue and Taxation Code; and ~~s~~S7ections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

Note: Text is from the website of the Office of Administrative Law as of 5/14/14. History was removed for ease of review.

Patno, Michael

From: Wade Downey <Wade.Downey@dsfgroup .com>
Sent: Thursday, August 28, 2014 4:49 PM
To: Patna, Michael
Cc: Royd Baik; Roderick Calub; Jim Fier
Subject: RE:hterested Parties Meeting - Regulation 1591 - Agenda and handouts
Attachments: DSF Proposed Revisions to 1591_August2014_final.docx

Michael,

I am back from vacation and finally have some language for you. As discussed, I had hoped to get this out before I left but ran out of time, so I apologize for the delay.

Anyways, after reflecting on the goal and discussing with our group, we think the required changes are pretty simple. See attached proposed language/changes to (a)(9)(A) and (c)(2). As recap, we like the idea of the reference to (c) being moved to the end of the sentence as Staff originally proposed. It just reads better, which I think we discussed. Also, we think adding a parenthetical reference to (c)(2) should clarify that "*or* article" is not intended to include fully implanted products consistent with Board decisions. During the appeals process, the language of (c)(2), specifically "or article", caused the greatest confusion. Adding a parenthetical, similar to other parts of (c)(2), stating….(unless product is fully implanted into the human body) would eliminate such confusion while maintaining the referencing and integrity of the regulation.

Beyond our proposed language, we wanted to point out and staff can decide how to address, that the proposed language may leave open whether fully implanted products of a temporary nature are covered by (a)(9)(A). The temporary aspect was not address in the BTM case and I am not aware of any other cases or Board decisions that have applied (a)(9)(A) to exempt temporary implants. We would be okay if Staff recommended or decided to include the term "permanently" (defined in annotation to be longer than 6 months) somewhere in the proposed (c)(2) parenthetical; either as "fully/permanently implanted" or "permanently and fully implanted".

If you would like to discuss further or want me to finalize in a letter with the comments let me know.

Thanks

Wade Downey
Downey, Smith & Fier
Direct: 562.249 .6002

(9) Medicines. “Medicines” means:

(A) ~~Except where taxable for all uses as provided in subdivision (c), a~~Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, ~~or~~ **unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses.**

(c) Exclusions from the Definition of “Medicines.”

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article (unless product is fully implanted into the human body) or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (division 9, commencing with Section 23000, of the Business and Professions Code).

From: Jacob Bholat
To: Patno, Michael
Subject: RE: Interested Parties Discussion - Regulation 1591
Date: Wednesday, September 03, 2014 8:14:10 PM

Hi Michael,

As part of the continued discussion we would propose the following edits to Regulation 1591. We don't believe that the minor revision proposed by staff clears up the continued confusion in the regulation.

Suggested revisions to (a)(9)(A)

(9) MEDICINES. "Medicines" means:

(A) Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, except where taxable as provided in subdivision (c) or

Suggested revisions to (b)(2)

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these types of items would be subject to tax, if intended for temporary placement.

Suggested revisions to (c)(2)

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof that are not fully and permanently implanted or their fully worn components. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

Please let me know if you would like any clarification or discussion regarding our suggestions.

Thank you,

Jacob Bholat
Partner
Equity Recovery Solutions Inc.

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949.295.1899
www.equityrs.com

From: Jacob Bholat [mailto:jbholat@equityrs.com]
Sent: Monday, August 11, 2014 9:50 AM
To: 'michael.patno@boe.ca.gov'
Subject: RE: Interested Parties Discussion - Regulation 1591

Hi Michael,

We greatly appreciate the opportunity to work with the BOE as you tackle potential revisions to help clarify the application of Regulation 1591. As discussed, below you will find our proposed language revision to 1591(b)(2) in bold and underlined. Rather than deal with each of the issues we presented in our original submission, we propose language that allows staff to use their judgment, when needed in working with taxpayers to analyze individual product types. Please forward to legal and staff to see if this might be an option to help clarify language and give staff the ability to deal with actual usage and changes in technology.

Thank you,

Regulation 1591(b)(2)

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax**, unless they are permanently implanted or the product use qualifies under another section in this regulation.**

Jacob
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